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TITLE: Modifiable Risk Factors for Lymphedema in Breast Cancer Survivors

PRINCIPAL INVESTIGATOR: Mary Anne Rossing, Ph.D., DVM
Kathleen E. Malone, Ph.D.

CONTRACTING ORGANIZATION: Fred Hutchinson Cancer Research Center
Seattle, WA 98109-1024

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Mary Anne Rossing, Ph.D., DVM
Kathleen E. Malone, Ph.D.

Email: mrossing@fhcrc.org

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14. ABSTRACT

Lymphedema of the arm is a consequence of breast cancer treatment that can result in substantial functional impairment and distress. In this study, women diagnosed with a first primary invasive breast cancer and treated with axillary lymph node dissection will be identified through a population-based cancer registry. The incidence and timing of arm edema will be assessed using physical measures (arm volume) and self-reported arm symptoms. In total, 443 women enrolled in the study; to date, 423, 404 and 292 women have completed their second, third, and fourth interview and measurements. A preliminary analysis, based on enrollment data, was presented at the DOD Era of Hope meeting in June, 2005. We found that increasing body mass was positively associated with the occurrence of arm swelling identified by self-report or by measured arm volume. Future analyses will assess changes in arm volume over time and relationships of arm swelling with treatment and lifestyle factors.

15. SUBJECT TERMS
Lymphedema, epidemiology, risk factors

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INTRODUCTION

Lymphedema of the arm is a common, yet dreaded consequence of breast cancer treatment that can result in substantial functional impairment and distress in affected women. Axillary surgery and radiation treatment are known risk factors for lymphedema. However, other potentially modifiable characteristics or behaviors that may influence risk of this condition have not yet been studied. In this study, we will assess whether modifiable factors, including body weight, physical activity, smoking, and breast reconstruction, influence risk of arm lymphedema among women treated for breast cancer. Women aged 21-74 years diagnosed with a first primary invasive breast cancer will be identified through a population-based cancer registry. Eligible women will be residents of King County, Washington. We aim to include approximately 500 women in the study cohort. Enrollment will be limited to women who have had axillary node dissection, as the occurrence of lymphedema is most common in these women. The incidence and timing of arm edema following breast cancer will be assessed using physical measures (arm volume) and self-report of symptoms, at regular intervals throughout the study. Each time they undergo arm measurement, women will complete questionnaires detailing and updating information on the exposures of interest and potential confounding factors. The study will be conducted over a 4-year period with an additional no-cost extension.

BODY

Research Accomplishments associated with tasks outlined in the Statement of Work are as follows:

Task 1. Develop Plan for Initial and Follow-up Interviews and Measurements, Months 1-3.

All of these tasks have been performed.

a. Final IRB approval will be obtained.

IRB approval has been obtained from the Fred Hutchinson Cancer Research Center and from the DOD.

b. Tracking system will be created to track patient contacts, recruitment, and interviews.

The tracking system for this study has been developed and is in use.

c. Cohort ascertainment through the CSS tumor registry will be initiated.

The full study cohort has been ascertained, and consists of 443 eligible women who completed a baseline interview.

d. Enrollment questionnaire will be developed, piloted and finalized.

The enrollment questionnaire has been developed, piloted and finalized, and all enrollment interviews have been completed.

e. *Interviewer will be trained on study procedures, measurement, and interview administration.*

Interviewer training on all study procedures, including measurement and interview administration, has been completed.

Task 2. Subject Recruitment and Initial Data Collection, Months 4-18

a. Potential study subjects will be contacted, and physician notification will be performed.
These procedures have been completed, with a final study cohort of 443 women. The first set of contacts with physicians and study subjects occurred after all Human Subjects approvals were obtained in May, 2003. As of December, 2006, we had identified 641 eligible women. The status of the 641 women in the study is as follows:

Deceased, before contacted:	10
Physician notification/ response in process:	0
Physician refusal:	29
Physician notified, subject not yet contacted:	0
Study subject refusal:	159
Subjects contacted, not yet enrolled:	0
Subjects contacted, enrollment interview scheduled:	0
Subjects contacted, enrollment interview complete:	443

b. Participant enrollment interviews and initial measurements will be conducted.
We have completed 443 enrollment interviews.

c. Follow-up questionnaires will be developed, piloted and finalized.
The first, second, and third follow-up questionnaires have been developed and finalized.

d. Data management and programming to create analytic data files for the enrollment questionnaire and arm measurement data will be performed.
These tasks have been completed, and preliminary data from the enrollment questionnaire and arm measures were presented at the DOD Era of Hope meeting in June, 2005. Additional variable creation for data analysis is ongoing.

Task 3. Follow-up Interviews and Data Collection, Months 10-45

a. Follow-up interviews and measurements will be conducted.

Follow-up interviews are nearly completed. To date, 423 first follow-up interviews and 404 second follow-up interviews have been conducted; the remaining women of the total study cohort of 443 women either refused or were unable to participate in follow-up interviews due to illness. Third follow-up interviews are still being conducted, with 292 of these completed by December, 2006. As reported last year, the conduct of follow-up interviews will extend several months into the current no-cost extension due to delays in study enrollment.

b. Data management and programming to create analytic data files from the follow-up questionnaires and repeat arm measurement databases will be performed.

These tasks are currently in progress.

c. Identification of women with lymphedema by arm volume measures, and comparison with self-report.

These tasks are also currently in progress, using the follow-up questionnaires and arm measures.

Task 4. Data Analysis and Report Writing, Months 37-48.

These tasks will be conducted during the no-cost extension of the project, reflecting the delay experienced in initiating participant enrollment.

KEY RESEARCH ACCOMPLISHMENTS

- 443 women enrolled in the study to date.
- First follow-up interviews conducted on 423 women.
- Second follow-up interviews conducted on 404 women.
- Third follow-up interviews currently in progress, with 292 conducted by December of 2006.
- Preliminary data analysis conducted and reported at the DOD Era of Hope meeting in June, 2005.

REPORTABLE OUTCOMES

Preliminary results were reported as a poster presentation and an oral presentation at the DOD Era of Hope Meeting in June 2005 (see abstract in Appendix).

CONCLUSIONS

There are no completed research results on which to base conclusions, and data analyses are currently in progress. Some preliminary findings of the study were reported at the DOD Era of Hope Meeting in June, 2005.

REFERENCES

None

APPENDICES

None